

REMARKS

This application has been reviewed in light of the Office Action mailed on November 2, 2006.

In the Office Action, Claim 1 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. However, Applicants submit that support for this recitation can be readily ascertained from the drawings of the application as filed. Accordingly, withdrawal of this rejection is respectfully requested.

In the Office Action, Claims 1-4, 10 and 13 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,342,397 to Guido in view of U.S. Patent No. 5,178,628 to Otsuka et al. It is respectfully submitted that the claimed disclosure is patentable over the combination of these two references. For example, the combination fails to disclose the recited “the needle end having a transition area whereby the needle end defines a substantially trapezoidal transverse cross-sectional dimension inclusive of the first and second cutting edges and being proximal of the transition area, and defines a substantially triangular transverse cross-sectional dimension inclusive of the first, second and third cutting edges and being distal of the transition area” as required by independent Claim 1. Both references are clearly devoid of this feature. Guido ‘397 teaches a needle having a cutting section of a constant shape throughout the length of the cutting section and terminating in a blunt tip. There is no transition within the cutting section of Guido ‘397 from one shape or cross-sectional dimension (e.g., trapezoidal) to another shape or cross-sectional dimensional (e.g. triangular) where each of the cross-sectional dimensions have cutting edges. Rather, with Guido ‘397, each of the cutting sections of the various embodiments terminates in a blunt surface devoid of cutting edges. With regard to Otsuka ‘628, Otsuka ‘628

teaches a needle with a triangular configuration adjacent its needle tip.

Contrary to the position taken in the Office Action, it is respectfully submitted that the combination of Guido '397 and Otsuka '628 is improper. In the Office Action, it is asserted that "it would have been obvious ... to incorporate the convex side surfaces extending to a pointed tip, as taught by Otsuka, to the device of Guido, since it was known in the art that needles should [be as] sharp as possible at the tip ... since sharper needles require less force and therefore [create] less tissue trauma." As appreciated, however, Guido '397 specifically teaches away from incorporating a distal needle end with cutting edges. Rather, Guido '397 discloses a needle having a needle end with a constant shape which leads to a blunt tip. Specifically, Guido emphasizes the importance of a blunt tip needle vis-à-vis a sharp tip throughout the application. For example, Guido teaches that the "blunt tip needle significantly increases the penetration force needed to penetrate a latex glove as compared to a sharp point needle" (column 2, lines 58-60); "needles of the present invention are less likely to penetrate the glove and skin of the user" (column 2, lines 26-27; and "although the blunt tip cutting edge needles of the present invention compromise initial forces of penetration, surgeons ... would be able to dramatically increase their safety factor ... during surgery as a result of the blunt tip needles of the present invention" (column 6, lines 30-36). It is therefore clear that Guido '397 is concerned with the safety provided by a blunt tip needle, rather than the reduction of forces provided by a sharp tip needle, and thus specifically teaches away from incorporating cutting edges in a needle end leading to a pointed tip. Thus, there would be no motivation to combine the teaching of Otsuka '628, i.e., a needle end having surfaces and cutting edges extending to an extreme pointed tip, to the device of Guido '397. Any suggestion otherwise is in direct contrast with the teachings of Guido '397

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and/or Otsuka '628, and thus contrary to the Federal Circuit's decision in *In re Fine*, 873 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), essentially holding that teaching away from the art is a *per se* demonstration of lack of *prima facie* obviousness. Therefore, for at least these reasons, Applicants believe Claim 1, and the claims which depend therefrom, are allowable over the art of record.

Claim 12 was rejected under 35 U.S.C. §103(a) over Guido '397 and Otsuka '628 and further in view of U.S. Patent No. 4,513,747 to Smith. Applicants believe Claim 12 is patentable for at least the reasons independent Claim 1 is patentable, as discussed hereinabove. Withdrawal of this rejection is respectfully requested.

Claims 5-7 and 14 were rejected under 35 U.S.C. §103(a) over Guido '397 and Otsuka '628 and further in view of U.S. Patent No. 5,762,811 to Munoz. Applicants believe Claims 5-7 and 14 are patentable for at least the reasons independent Claim 1 is patentable, as discussed hereinabove. Withdrawal of this rejection is respectfully requested.

Claims 8 and 9 were rejected under 35 U.S.C. §103(a) over Guido '397, Otsuka '628 and Munoz '911 and further in view of U.S. Patent No. 4,133,339 to Naslund. Applicants believe Claims 8 and 9 are patentable for at least the reasons independent Claim 1 is patentable, as discussed hereinabove. Withdrawal of this rejection is respectfully requested.

Claim 11 was rejected under 35 U.S.C. §103(a) over Guido '397 and Otsuka '628 and further in view of U.S. Patent No. 4,524,771 to McGregor et al. Applicants believe Claim 11 is patentable for at least the reasons independent Claim 1 is patentable, as discussed hereinabove. Withdrawal of this rejection is respectfully requested.

Claims 15-20 were rejected under 35 U.S.C. §103(a) over Guido '397 in view of Munoz '811. Our comments with respect to Guido '397 presented hereinabove are repeated herein. With respect to Munoz '811, Munoz '811 discloses a photoetching process for needle fabrication.

It is respectfully submitted that the present invention as claimed is patentably distinguishable over the combination of these references. For example, the combination of Guido '397 and Munoz '811 fails to disclose the recited "the second needled end having a transition area whereby the second needle end defines a substantially trapezoidal transverse cross-sectional dimension inclusive of the first and second cutting edges and being proximal of the transition area, and defines a substantially triangular transverse cross-sectional dimension inclusive of the first, second and third cutting edges and being distal of the transition area" as required by independent claim 15. Both Guido '397 and Munoz '811 are devoid of regions of the needle end which are inclusive of cutting edges and having different cross-sectional shapes, e.g., a substantially trapezoidal leading to a triangular cross-section. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in the application are in condition for allowance and patentably distinguishable over the art of record.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, she is requested to call the Applicants' undersigned attorney at her convenience.

Respectfully submitted,

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